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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,811	PAULY ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-22,24-26 and 28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-22,24-26 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 7/28/2008. Claims 19 and 27 are cancelled. Claims 20-22, 24, 26, 28-31, 33, and 38 are amended, overcoming the previous claim objections. Claims 39-40 are new. **Claims 2-22, 24-26, and 28-40** remain pending and under prosecution.

Specification

2. The disclosure is objected to because of the following informalities: the brief description of the drawings on p.14 does not appear to mention Figure 8, although it is described in greater detail in the body of the specification. Although Applicant states that said preliminary amendment filed 4/8/2005 includes a description of Figure 8, it does not appear that the copy of said preliminary amendment on record contains said description. Applicant is requested to review said preliminary amendment and specifically point out where said description is included or submit a new amendment containing such.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 39, 20-22, and 24-26** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Specially, Claim 39 recites in step (d) "analyzing the electrical signals detected…prior to stimulation of the skin substrate." However, as best understood by the Examiner, it is believed that stimulation always occurs, both prior to and after topical application of the compound on the skin substrate, for example as described in the description for Figures 7-8. As such, the following claims have been interpreted as such. However, if this interpretation is incorrect, Applicant is respectfully requested to point out portions of the specification disclosing the desired interpretation, or alternatively, to amend the claims to reflect the actual method of operation of the instant application.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claims 19-21, 26, 31-32, and 38-40** rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US Pat No. 5540235) in view of Querleux et al (US Pub No. 20030225326), further in view of T.K. Cowell (US Pat No. 3468302).

8. In regards to **Claim 39**, Wilson discloses a method for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said method comprising:

(a) detecting the electrical signals from the nerves, in vivo, in a first region of a skin substrate by applying a first non-invasive electrode (11) to a first measuring point and a second non-invasive electrode (11) at a second measuring point in the first region of the skin substrate, best seen in Figure 1;

(b) subjecting the skin substrate to stimulation (7), in vivo, in a second region of the skin substrate by applying a first non-invasive stimulation electrode (38) at a first measuring point and second non-invasive stimulation electrode (38) at a second measuring point in the second region of the skin substrate, best seen in Figure 1 and 3;

(c) recording the electrical signals detected by the first and second non-invasive electrodes (Col.2: 28-36);

(d) determining with an evaluation circuit 3 the conductivity of the nerves in the first region of the sin substrate (Col.2: 28-42; Col.5: 62-67) by analyzing the electrical signals detected, the evaluation circuit comprising at least one amplifying element (51), at least one processing element (53), and at least one microprocessor or computer (1) including at least one recording element (memory) and a display (Figure 1), best seen in Figure 6.

9. However, Wilson does not disclose analyzing the electrical signals detected prior to topical application of a compound to the skin substrate and stimulation, and after topical application of a compound and stimulation and determining the reactivity and/or hypersensitivity of the skin substrate based on the analyzed signals. Querleux et al teach that the reactivity and/or hypersensitivity of skin substrate is determined by analyzing a first set of information, i.e. brain

images, gathered before topical application of a compound to the skin substrate, with a second set of information gathered after topical application of the compound to the skin substrate (¶0007, 0009, 00014, abst), as an effective method to determine skin reactivity and/or hypersensitivity. Querleux et al also teach that a technique other than brain images may be used for the first set of information (¶0014). T.K. Cowell teach that passing a current between two separate areas of the skin, applying a stimulus, and then measuring the change in voltage effectively allows the sensitivity of substances such as drugs on subjects to be evaluated (Col.1: 44-62).

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilson such that a topical application of a compound that is applied to the skin substrate is compared with information gathered before application with information gathered after application to effectively determine the reactivity and/or hypersensitivity of the skin substrate based on the analyzed signals, as taught by Querleux et al, such that the reactivity and/or hypersensitivity of the skin substrate is determined by analyzing the electrical signals as taught by T.K. Cowell, detected prior to topical application of the compound and stimulation, and after topical application of the compound and stimulation, as an effective means to measure the reactivity and/or hypersensitivity of the skin substrate.

11. In regards to **Claim 20**, Wilson discloses the stimulation (7) (Col.6: 42-43) comprises electrical stimulation (Col.2: 28-35).

12. In regards to **Claim 21**, Wilson in combination with Querleux et al and T.K. Cowell disclose the electrical stimulation (7) is provided by a stimulation circuit comprising at least two stimulation electrodes (38) in contact with an area of the skin substrate subject to the stimulation and an electrical stimulator (33) connected to the microprocessor (1), best seen in Figures 1 and 3 (Col.6: 42-49).

13. In regards to **Claim 26**, Wilson discloses applying a weak alternating current (Col.5: 50) to the first non-invasive electrode and measuring the impedance of the skin substrate.

14. In regards to **Claim 40**, Wilson discloses an apparatus for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said apparatus comprising:

(a) a first non-invasive measuring electrode (11) and a second non-invasive measuring electrode (11) for detecting electrical signals, in vivo, from the nerves in a first region of a skin substrate (Col.2: 28-37), best seen in Figure 1;

(b) an electronic stimulator (7) connected to a first non-invasive stimulation electrode (38) and a second non-invasive stimulation electrode (38) for applying electrical stimulation to the skin substrate in a second region of the skin substrate, best seen in Figure 1 and 3;

(c) at least one reference electrode (11) for detecting electrical signals from the nerves, best seen in Figure 1 (Col.2: 30);

(d) a circuit connected to the first one non-invasive measuring electrode and the second non-invasive measuring electrode, the electronic stimulator, and the at least one reference electrode, for determining the conductivity of the nerves in the first region of the skin substrate

by analyzing the electrical signals detected by said electrodes, the circuit comprising at least one amplifying element (51), at least one processing element (53), and at least one microprocessor or computer (1) that includes at least one recording element (memory), best seen in Figure 6, and a display (abst), wherein said circuit is capable of creating and displaying a curve representative of differentials in the signals detected by the first and second non-invasive measuring electrode as a function of time. It is noted that Wilson discloses all the claimed structural elements and are thus capable of any use recitation.

15. However, Wilson does not disclose analyzing the electrical signals detected prior to topical application of a compound to the skin substrate and stimulation, and after topical application of a compound and stimulation and determining the reactivity and/or hypersensitivity of the skin substrate based on the analyzed signals. Querleux et al teach that the reactivity and/or hypersensitivity of skin substrate is determined by analyzing a first set of information, i.e. brain images, gathered before topical application of a compound to the skin substrate, with a second set of information gathered after topical application of the compound to the skin substrate (¶0007, 0009, 00014, abst), as an effective method to determine skin reactivity and/or hypersensitivity. Querleux et al also teach that a technique other than brain images may be used for the first set of information (¶0014). T.K. Cowell teach that passing a current between two separate areas of the skin, applying a stimulus, and then measuring the change in voltage effectively allows the sensitivity of substances such as drugs on subjects to be evaluated (Col.1: 44-62).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilson such that a topical application of a

compound that is applied to the skin substrate is compared with information gathered before application with information gathered after application to effectively determine the reactivity and/or hypersensitivity of the skin substrate based on the analyzed signals, as taught by Querleux et al, such that the reactivity and/or hypersensitivity of the skin substrate is determined by analyzing the electrical signals as taught by T.K. Cowell, detected prior to topical application of the compound and stimulation, and after topical application of the compound and stimulation.

17. In regards to **Claim 31**, Wilson discloses at least two non-invasive measuring electrodes 11, best seen in Figure 1, wherein at least one non-invasive measuring electrode is capable of measuring impedance of the skin substrate.

18. In regards to **Claim 32**, Wilson discloses at least one adjustable voltage generator (35) associated with at least one transmitting aerial (15) erected in proximity to the at least one non-invasive measuring electrode (11) capable of measuring impedance, best seen in Figure 1A and 3A.

19. In regards to **Claim 38**, Wilson discloses the at least one processing element comprises an analog/digital converter (52).

20. **Claims 22, 24-25, and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Querleux et al and T.K. Cowell, further in view of Zealear et al (US Pat No. 4817628).

21. In regards to **Claim 22**, Wilson in combination with Querleux et al and T.K. Cowell disclose the skin substrate is subjected to a stress (the topical application of the compound) and the electrical signals detected by the first and second non-invasive electrodes with the stress is compared to the electrical signals detected by the first and second non-invasive electrodes without the stress. However, Wilson in combination with Querleux et al and T.K. Cowell do not explicitly disclose the skin substrate is facial skin. Querleux et al disclose that the topical application of the compound may be a cosmetic, which is known to one of ordinary skill in the art as being applied to facial skin (¶0031). Zealear et al disclose electrodes placed on facial skin substrate to detect an electrical signal of a sensory nerve of a facial skin substrate, best seen in Figure 1 (abst), to determine the conductivity of the nerves (Col.10: 22-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilson and Querleux et al and T.K. Cowell to subject a facial skin substrate, as taught by Zealear et al, to stress and the electrical signals detected by the first and second non-invasive electrodes with the stress is compared to the electrical signals detected by the first and second non-invasive electrodes without the stress, to effectively determine the sensitivity of facial skin.

22. In regards to **Claim 24-25**, Zealear et al disclose the first non-invasive electrode is positioned such that it is capable of capable of transmitting signals representative of the electrical activity of at least of one branch of a facial trigeminal nerve selected from the group consisting of an ophthalmic branch, a maxillary branch, a mandibular branch and combination thereof, and in particular the maxillary branch. Although Zealear et al do not explicitly disclose electrical

contact with the maxillary branch, it is obvious to one of ordinary skill in the art that the placement of said electrodes, best seen in Figure 1, would enable electrical contact with said maxillary branch due to its known location on the face coinciding with that of said electrodes.

23. In regards to **Claim 30**, Wilson in combination with Querleux et al and T.K. Cowell disclose the apparatus above but does not disclose at least one non-invasive measuring electrode connected to an adjustable connected to an adaptable holder. Zealear et al teach an adaptable holder (66) and an adjustable arm having a first and second end, wherein the first end is connected to the adaptable holder, and wherein a least one electrode is connected to the second end, best seen in Figure 1, as an effective means to secure the electrodes to the head to allow electrical contact with the facial skin and nerves (Col. ¶0035). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place at least one non-invasive measuring electrode of Wilson in combination with Querleux et al and T.K. Cowell on an adjustable arm connected to an adaptable holder described above, as taught by Zealear et al, as an effective means to secure the at least one non-invasive measuring electrode to the head for the desired facial nerve analysis.

24. **Claims 28-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Querleux et al and T.K. Cowell, further in view of Dunseath, Jr (US Pat No. 5003978).

25. Wilson as modified by Querleux et al and T.K. Cowell in the manner above disclose at least one non-invasive measuring electrode above but does not disclose said electrode as non-polarizable or comprising a material selected from the group consisting of stainless steel,

tungsten, noble metals and mixtures thereof. Dunseath, Jr teach the use of a non-polarizable electrode for advantages such as the ability to withstand high voltage overloads (Col.1: 36-44) comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof (Col.5: 1-5) as effective materials for said non-polarizable electrode. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least one non-invasive measuring electrode of Wilson as modified by Querleux et al and T.K. Cowell non-polarizable and comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof, as taught by Dunseath, Jr, as an effective means to obtain the benefits associated with use of a non-polarizable electrode such as high voltage capacity.

26. **Claims 33-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Querleux et al and T.K. Cowell, further in view of Miyata et al (US Pat No. 6026321).

27. In regards to **Claim 33**, Wilson as modified by Querleux et al and T.K. Cowell in the manner above disclose at least one amplifying element comprising at least one preamplifier (51) but do not disclose the at least one preamplifier having a high input impedance over a voltage range of from -3 to +3 volts. Miyata et al disclose an amplifier having a high input impedance over a voltage range of from -3 to +3 volts (Col.6) as an effective value for skin measuring electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the at least one preamplifier of Wilson as modified by Querleux

et al and T.K. Cowell have a high input impedance over a voltage range of from -3 to +3 volts as taught by Miyata as an effective value for the skin measuring application.

28. In regards to **Claim 34**, Wilson discloses the at least one preamplifier (51) is connected directly to the at least one reference electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4d.

29. In regards to **Claim 35**, Wilson discloses the at least one preamplifier (51) is connected directly to the non-invasive measuring electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4D.

30. **Claims 36-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Querleux et al, T.K. Cowell, and Miyata et al, further in view of Bergman et al (US Pat No. 4257010).

31. In regards to **Claim 36**, Wilson as modified by Querleux et al, T.K. Cowell, and Miyata et al in the manner above disclose at least one preamplifier connected to the non-invasive measuring electrode but do not disclose the at least one preamplifier is connected to the non-invasive measuring electrode by a shielded cable. Bergman et al disclose connecting wires (13a,b) surrounded by shielding (16) to prevent interference between the wires (Col.5: 44-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Wilson as modified by Querleux et al, T.K. Cowell, and Miyata et al to

connect the at least one preamplifier to the non-invasive measuring electrode by a shielded cable as taught by Bergman et al to prevent unwanted interference between proximal connecting wires.

32. In regards to **Claim 37**, Wilson as modified by Querleux et al, T.K. Cowell, Miyata et al, and Bergman et al above disclose the shielded cable comprises a shield connected to an output of the at least one amplifying element (Col.5: 50-58).

Response to Arguments

33. Applicant's arguments with respect to claims 2-22, 24-26, and 28-40 have been considered but are moot in view of the new ground(s) of rejection.

34. It is noted that although the Examiner does not necessarily agree with Applicant's arguments regarding the use of Querleux et al, the Examiner has set forth new grounds of rejections using at least T.K. Cowell in an effort to advance the prosecution of the instant application. For example, it is noted that Applicant's disclosure appears to state that it is known that besides electrical signals detected by measuring electrodes, electrical activities of the skin or brain could also be analyzed using magnetic field generation. See p.7 of Applicant's disclosure.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736